

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF SAN BERNARDINO COUNTY, CALIFORNIA
AND RECORD OF ACTION**

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February 25, 2003

FROM: JAMES A. FELTEN, Public Health Programs Administrator
Department of Public Health

SUBJECT: CONTRACT WITH CALIFORNIA DEPARTMENT OF HEALTH SERVICES FOR
HIV-1 DRUG RESISTANCE TESTING BY GENOTYPING (AGREEMENT
NUMBER 02-25860)

RECOMMENDATION:

1. Approve contract with the State Department of Health Services in an amount not to exceed \$500,000, for the Department of Public Health to conduct HIV-1 drug-resistance testing services for the period July 1, 2002 through June 30, 2003.
2. Authorize the Auditor/Controller-Recorder to increase revenue and appropriations in the Department of Public Health's FY 2002-2003 budget by \$475,000 as detailed in the Financial Impact Section (four votes required).
3. Find it is in the best interest of the County to utilize Visible Genetics as a sole source provider for drug resistance reagents and supplies.
4. Authorize County Purchasing Agent to increase Purchase Order (PO) #T0570 not to exceed \$25,000 to Visible Genetics for drug resistance reagents and supplies not to exceed \$100,000.

BACKGROUND INFORMATION: On April 2, 2002, the Board approved submission of an application by the Department of Public Health (Department) to the California Department of Health Services (DHS) to conduct HIV-1 drug resistance testing by genotyping for the period of July 1, 2002 through June 30, 2003. The Department's Laboratory is one of ten laboratories statewide contracted by the State to perform this specialized test. The test detects the presence of drug-resistant virus in patient's blood and assists health care providers in selecting an effective anti-retroviral regimen.

As specified by the State, the Department's Laboratory will conduct HIV-1 resistance testing for eligible individuals served by the Department and the AIDS programs of San Bernardino and Riverside Counties. The State will reimburse the Department at the fixed rate of \$400 per test, for a maximum amount of \$500,000. The State office of AIDS allocates annual funding for HIV-1 drug resistance testing to contract laboratories based on the estimated number of tests that will be required for each local health jurisdiction. The Department included \$25,000 in its FY 2002-2003 budget to conduct a total of 50 HIV-1 drug resistance tests, but the State has decided to provide the Department with sufficient financial resources to conduct up to 1,250 tests.

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The discrepancy in anticipated number of tests is due to different methods of calculation. Currently, there are ten laboratories that are able to perform this test. The State allows each physician and patient the flexibility to choose which of the ten laboratories will analyze the specimen. The contract reflects a maximum number of 1,250 tests so that DHS will have necessary resources to allow maximum flexibility to physicians and patients statewide. However, the Department expects 50-100 tests based on the actual number of tests performed last year.

The Department estimates that it can meet the anticipated demand for testing with current staff. Therefore, it is requested that the operating budget increase by only \$78,000, which will be used to increase the PO with Visible Genetics from \$25,000 to \$100,000 and to pay for \$3,000 of training and travel to certify two Public Health Microbiologists to conduct these tests. Training additional (existing) staff will provide additional flexibility in assigning test activities. The remaining \$397,000 available under the terms of the contract will be budgeted in contingencies.

Should the volume of tests exceed expectations, the Department will return to the Board to ask for contract staff and to redirect those contingency funds into operations.

County Policy #11-04 requires Board of Supervisors approval for sole source and noncompetitive purchases of goods and supplies in excess of \$25,000 per vendor per fiscal year. Approval of the fourth recommendation authorizes a sole source purchase order to Visible Genetics. The sole source recommendation is based on consultation with several authorities to find out if other systems have been approved by the Food and Drug Administration (FDA) for genotyping. Only Visible Genetics has the complete, full FDA approval. A second system recently received FDA approval with extensive limitations and limited availability that make it unsuitable for the Department's laboratory at this time.

Two certified Public Health Microbiologists have been trained and certified to perform genotyping by the Visible Genetics technology. They have participated in proficiency testing using the Visible Genetics system and procedures and have acquired extensive experience using the Visible Genetics system and procedures. Travel and training funds are needed to send two additional Public Health Microbiologists to Atlanta, Georgia to receive training at the Visible Genetics Training center and to become certified to conduct the test. This training is available only in Atlanta, Georgia.

The Department of Public Health received the contract from the State on October 11, 2002. This item is being brought forward at this time due to departmental delays in the item review process.

REVIEW BY OTHERS: This item has been reviewed by County Counsel (Charles Larkin, Deputy County Counsel) on January 30, 2003. This item has also been reviewed by the County Administrative Office (Beatriz Valdez, Administrative Analyst) on February 13, 2003 and Purchasing Department (Aurelio De La Torre, Director) on January 30, 2003.

FINANCIAL IMPACT: Approval of this item will result in no local cost to the County. Expenditures are fully reimbursable through the contract with the State. The Department has included \$25,000 (of the total \$500,000) in its approved FY 2002-2003 budget to conduct HIV-1 drug resistance testing. Expenditures, contingencies, and revenues in the amount of \$475,000 are additional to the Department's approved FY 2002-2003 budget.

Budget increases are requested as follows:

	<u>Fund</u>	<u>Dept</u>	<u>Org</u>	<u>Appr</u>	<u>Object</u>	<u>Amount</u>
Appropriations:						
Air Travel	AAA	PHL	PHL	200	2945	\$1,200
Training	AAA	PHL	PHL	200	2140	\$1,800
Laboratory Supplies	AAA	PHL	PHL	200	2840	\$75,000
				Subtotal – 200s		\$78,000
Contingencies	AAA	PHL	PHL	600	6000	\$397,000
				Subtotal – 600s		\$397,000
Total Appropriation Increase						\$475,000
Revenues:						
State Aid-DHS	AAA	PHL	PHL		8710	\$475,000
				Total Revenue Increase		\$475,000

Cost Reduction Review: The County Administrative Office has reviewed this agenda item and concurs with the Department's proposal and recommends action based on the program producing revenue that fully offsets all costs associated with the program.

SUPERVISORIAL DISTRICT (S): All

PRESENTER: James A. Felten, Public Health Programs Administrator (909) 387-9146